MAY 1 8 2000

K001086

DIAGNOSTIC SYSTEMS LABORATORIES, Inc. www.DSLabs.com
445 Medical Center Blvd | Webster, Texas 77598 USA | +1.281.332.9678 tel | 1.800.231.7970 toll free | +1.281.338.1895 fax | mktg@DSLabs.com

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device:	DSL 10-4900 ACTIVE™ Free Testosterone Coated Well EIA Kit
Classification Name:	Enzyme Immunoassay for Free Testosterone
Analyte Name:	Testosterone
Regulatory Class:	I

Submitter: John Class
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598
Phone: 281-332-9678

Date: May 4, 2000

The DSL ACTIVE™ Free Testosterone EIA kit was developed for the quantitative measurement of active Free Testosterone in human serum or plasma. This EIA format is a capture assay. Anti-human Free Testosterone antibody to Free Testosterone is immobilized to the surface of the wells. Free Testosterone in the standards or samples is "sandwiched" between this antibody and the anti-human Free Testosterone antibody labeled for detection.

The DSL ACTIVE™ Free Testosterone EIA assay is intended for the quantitative determination of active Free Testosterone in human serum or plasma. This assay is intended for *in vitro* diagnostic use. Free Testosterone measurements are used as an aid in the diagnosis and management of hirsutism.

The DSL ACTIVE™ Free Testosterone EIA is substantially equivalent to the DSL Free Testosterone RIA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=69) were collected and assayed simultaneously by both methods. Linear regression analysis of the results obtained for the comparison with the Free Testosterone assay gave the equation $Y=0.90(X) + 0.3002$ with a correlation coefficient of $(r) = 0.94$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2000

Mr. John G. Class
Director of Regulatory Affairs
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598

Re: K001086
Trade Name: DSL Free Testosterone EIA
Regulatory Class: I (reserved)
Product Code: CDZ
Dated: May 4, 2000
Received: May 5, 2000

Dear Mr. Class:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001086

Device Name: DSL Free Testosterone EIA

Indications For Use:

The DSL-10-4900 Free Testosterone Enzyme Immunoassay provides materials for the quantitative measurement of free testosterone in serum or plasma. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis and management of hirsutism.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number ~~K001086~~ K001086

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

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